Complete Summary

GUIDELINE TITLE

Kidney neoplasms - benign and malignant.

BIBLIOGRAPHIC SOURCE(S)

Kidney neoplasms - benign and malignant. Philadelphia (PA): Intracorp; 2005. Various p. [18 references]

GUIDELINE STATUS

This is the current release of the guideline.

All Intracorp guidelines are reviewed annually and updated as necessary, but no less frequently than every 2 years. This guideline is effective from April 1, 2005 to April 1, 2007.

COMPLETE SUMMARY CONTENT

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
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SCOPE

DISEASE/CONDITION(S)

Benign and malignant kidney neoplasms, including

- Benign tumors
 - Papillary adenoma
 - Angiomyolipoma
 - Oncocytoma
- Malignant tumors
 - Renal cell carcinoma, including
 - Clear cell carcinoma
 - Chromophilic or papillary carcinoma
 - Chromophobic carcinoma

- Oncocytic carcinoma
- Collecting duct carcinoma
- Will's tumor
- Urothelial tumors of the calyces and pelvis

GUI DELI NE CATEGORY

Diagnosis Evaluation Management Treatment

CLINICAL SPECIALTY

Family Practice Internal Medicine Nephrology Oncology Surgery

INTENDED USERS

Allied Health Personnel Health Care Providers Health Plans Hospitals Managed Care Organizations Utilization Management

GUIDELINE OBJECTIVE(S)

To present recommendations for the diagnosis, treatment, and management of benign and malignant kidney neoplasms that will assist medical management leaders to make appropriate benefit coverage determinations

TARGET POPULATION

Individuals with benign and malignant kidney neoplasms

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

- 1. Physical examination and assessment of signs and symptoms
- 2. Diagnostic tests:
 - Urinalysis
 - Bone scan
 - Computed tomography (CT) scan
 - Chest x-ray (CXR)
 - Abdominal ultrasound (US)
 - Abdominal magnetic resonance imaging (MRI)

- Blood work
 - Complete blood count (CBC)
 - Liver chemistries (alkaline phosphatase [ALP], glutamyl transferase [GGT])
- Removing the entire lesion surgically and examining the complete specimen

Management/Treatment

- 1. For angiomyolipoma
 - Observation
 - Angiographic embolization
 - Surgical removal
- 2. For solid renal mass without evidence of systemic spread of the neoplasm
 - Partial (nephron-sparing) or radical nephrectomy
 - Percutaneous biopsy and pathology analysis
 - Nephroureterectomy
- 3. For confirmed metastatic renal cell carcinoma
 - Immunotherapy or radiation therapy
 - Palliative removal of the primary tumor to relieve paraneoplastic syndromes or local tumor pain
- 4. Physical therapy, if indicated
- 5. Referral to specialists
- 6. Case management strategies, including case initiation, case management focus, and discharge

MAJOR OUTCOMES CONSIDERED

Diagnostic and prognostic utility of diagnostic tests

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Searches were performed of the following resources: reviews by independent medical technology assessment vendors (such as the Cochrane Library, HAYES); PubMed; MD Consult; the Centers for Disease Control and Prevention (CDC); the U.S. Food and Drug Administration (FDA); professional society position statements and recommended guidelines; peer reviewed medical and technology publications and journals; medical journals by specialty; National Library of Medicine; Agency for Healthcare Research and Quality; Centers for Medicare and Medicaid Services; and Federal and State Jurisdictional mandates.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not stated

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

A draft Clinical Resource Tool (CRT or guideline) is prepared by a primary researcher and presented to the Medical Technology Assessment Committee or the Intracorp Guideline Quality Committee, dependent upon guideline product type.

The Medical Technology Assessment Committee is the governing body for the assessment of emerging and evolving technology. This Committee is comprised of a Medical Technology Assessment Medical Director, the Benefit and Coverage Medical Director, CIGNA Pharmacy, physicians from across the enterprise, the Clinical Resource Unit staff, Legal Department, Operations, and Quality. The Intracorp Guideline Quality Committee is similarly staffed by Senior and Associate Disability Medical Directors.

Revisions are suggested and considered. A vote is taken for acceptance or denial of the CRT.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Diagnostic Confirmation

Subjective Findings

- Flank pain (40 to 50%)
- Report of blood-tinged urine
- Report of palpable mass in flank
- Night sweats
- Bony pain (suggests metastasis)
- Fatigue
- Unintentional weight loss

Objective Findings

- Hematuria (gross or microscopic) most common presenting complaint
- Renal colic (flank pain)
- Weight loss (30 to 35%)
- Hypochromic anemia
- Palpable flank mass
- Fever of undetermined origin (FUO)
- Sudden onset of left varicocele
- Paraneoplastic syndrome: symptoms may include
 - Fever of unknown origin
 - Polycythemia
 - Hypercalcemia (5%)
 - Stauffer's syndrome (reversible hepatic dysfunction evidenced by abnormal liver function tests [LFTs], 7 to 15%)
 - Erythrocytosis
 - Protein-wasting enteropathy
 - Neuromyopathy
 - Amyloidosis (2%)

Diagnostic Tests

- Urinalysis
 - If hematuria is present, further investigation is warranted.
- Bone scan

- Bone scan is indicated if serum alkaline phosphatase (ALP) is abnormal.
- Computed tomography (CT) scan: see Intracorp Imaging: Abdomen and Viscerae guideline
 - Areas of fat identified in the tumor during abdominal CT, strongly predictive of angiomyolipoma diagnosis
 - Abdominal CT provides staging information including extent of disease, information regarding liver metastasis, and inferior vena cava (IVC) disease.
 - Head or chest CT indicated when metastases are suspected
- Chest x-ray (CXR)
 - CXR is performed to rule out pulmonary metastases.
- Abdominal ultrasound (US) see Intracorp Imaging: Abdomen and Viscerae guideline
 - Abdominal US is useful in differentiating between cysts and masses.
- Abdominal magnetic resonance imaging (MRI) see Intracorp Imaging: Abdomen and Viscerae guideline
 - Abdominal MRI is performed if CT scan is indeterminate in ruling out inferior vena cava (IVC) disease.
- Blood work
 - Complete blood count (CBC)
 - Critical values: hemoglobin (Hgb) <9 gm/dL; hematocrit (Hct)
 <25 volume %; platelets (Plts) = 30,000/mm³
 - Hct = 30 volume % indicates moderate to severe anemia
 - Anemia can cause confusion, congestive heart failure (CHF), fatigue, and shortness of breath (SOB).
 - Liver chemistries
 - Alkaline phosphatase (ALP); Normals: Adult: 17 to 142 U/L
 - Glutamyl transferase (GGT); Normals: Men: 5 to 85 U/L, Women: 5 to 55 U/L
 - Abnormal liver enzyme results may indicate metastatic disease.
- The only reliable way to rule out renal cell carcinoma is to remove the entire lesion surgically and examine the complete specimen. Biopsy of renal mass has little, if any, role in ruling out renal cell carcinoma. It is often possible to make the diagnosis of angiomyolipoma, a common benign renal tumor, based on presence of fat on the CT scan. However, if there is any doubt in this finding, the mass should be treated as if it is a renal cell carcinoma and surgically removed

Differential Diagnosis

- Malignant conditions
 - Renal cell carcinoma
 - Squamous cell carcinoma of the collecting system
 - Transitional cell carcinoma of the renal pelvis or collecting system
 - Metastatic tumor from another primary site (e.g., breast, lung, adrenal)
 - Fibrosarcoma
 - Lymphoma
 - Nephroblastoma

- Benign masses
 - Renal calculi/nephrolithiasis [kidney stones] (see Intracorp Nephrolithiasis guideline)
 - Acute focal bacterial nephritis
 - Renal tuberculosis
 - Infrarenal hematoma
 - Multi-locular renal cyst
 - Angiomyolipoma
 - Oncocytoma
 - Renal adenoma

Treatment Options

Treatment depends on suspected diagnosis and estimated stage of disease

- Angiomyolipoma (if diagnosis is made unequivocally on CT scan)
 - If lesion < 4 cm, observation is appropriate.
 - · Care setting: unrestricted
 - If the lesion equals 4 cm or larger and the patient is asymptomatic, observation may be appropriate, although some favor surgical removal.
 - If the lesion >4 cm and the patient is symptomatic
 - Angiographic embolization --or--
 - Surgical removal
 - Surgery Setting: acute inpatient
- Solid renal mass, seen on radiographic studies without evidence of systemic spread of the neoplasm: may recommend partial (nephron-sparing) or radical nephrectomy (see the Intracorp guideline Nephrectomy)
 - Alternately, percutaneous biopsy and pathology analysis of the renal mass to make definitive diagnosis
 - If a transitional cell carcinoma of the renal pelvis or collecting system is encountered during surgery, nephroureterectomy should be performed.
 - Surgery Setting: acute inpatient
 - Percutaneous Biopsy Setting: clinic or free-standing outpatient unless patient acutely ill requiring hospitalization
- Confirmed metastatic renal cell carcinoma, consider immunotherapy or radiation therapy
 - Care setting: physician's office or home care; clinic or free-standing outpatient
- Symptomatic paraneoplastic syndromes or local tumor pain, consider palliative removal of the primary tumor
 - Care setting: acute inpatient

Duration of Medical Treatment

- Medical Optimal: 5 day(s), Maximal: 42 day(s)
 - Maximal duration is lifetime.

Additional information regarding primary care visit schedules, referral options, specialty care, physical therapy, and durable medical equipment is provided in the original guideline document.

The original guideline document also provides a list of red flags that may affect disability duration, and return to work goals, including

- Resolving renal insufficiency and hypertension
- Resolving pain, infection, or bleeding
- After hospitalization for partial nephrectomy
- After hospitalization for complete nephrectomy

Note: Some patients with this condition may never return to work.

<u>Case Management Directives</u> (refer to the original guideline for detailed recommendations)

Case Initiation

Establish Case

- Document baseline information, history, key physical findings, patient's understanding, and safety factors.
- Refer to Chemotherapy Chart in the original guideline document.
- The American Joint Committee on Cancer encourages use of the "TNM" classification system (T=primary tumor size; N=lymph node involvement; M=metastasis).
- Provide contact information for local and national support groups.

Coordinate Care

- Advocate for patient by managing utilization and charges.
- Document treatment plan.

Case Management Focus

Activity Deficit

 Document activity alteration as none, mild, moderate, severe, dependent, or bed-bound (based on most recent performance status) and interventions required.

Chemotherapy Intolerance

 Assess status, acute versus chronic, of toxic side effects on rapidly growing tissues, including bone marrow, epithelium, hair, sperm, and document intervention recommended.

Hemodynamic Instability

• Document bleeding complications, severity, and intervention recommended.

Immune Compromised

 Document establishment of protective isolation measures for a white blood cells count (WBC) less than 1,000/mm³, implying dangerous susceptibly to infection.

Inadequate Nutrition

- Assess for need to increase fluids if mucus present after ileal conduit diversion or when encrustation present at insertion sites.
- Instruct patient to decrease stress incontinence by avoiding gas-forming foods and air-swallowing activities (e.g., chewing gum and smoking).
- Use optimal goal of remaining within 10% of pretreatment weight to document hydration and nutrition deficit as mild, moderate, severe and response needed.

Mental and Emotional Alteration

- Ensure accurate diagnosis of any change in mental status.
- Document baseline or optimal mental and emotional functioning and their alterations due to cancer presence, comorbidity, surgery, or treatments.
- Assess and respond appropriately to the degree of debility caused by alterations listed in the original guideline document through benefit coordination or community resource activation.

Pain Control

- Report possible kidney tumor impingement.
- Evaluate reports of pain for post-infarction syndrome 2 to 3 days after surgery: flank or abdominal pain with elevated temperature and gastrointestinal complaints.
- Document optimal pain management by characterizing severity and interventions undertaken to remedy or manage pain.

Oncologic Emergencies

- Immediately refer patient to attending physician or surgeon or activate emergency medical technician (EMT) system as needed for hyperchloremic acidosis; infection (bacterial reflux from colon, peritonitis); post-infarction syndrome (see Pain section above); pyelonephritis (renal calculi); small bowel obstruction (paralytic ileus); stomal gangrene; stomal stenosis; urethral obstruction; wound dehiscence.
- Document presence of or developing oncologic emergencies and report to attending physician, surgeon, or activate EMT system as necessary.

Radiation Intolerance

- Document presence and severity of radiation side effects.
- Initiate early interventions for complications of radiation therapy.

Respiratory Instability

• Document respiratory deficit as mild, moderate, severe, and dependent, and respiratory rehabilitation enhancement measures.

Skin Integrity Deficit

- Assess intensity of nursing care needed after type of renal diversion as infrequent, intermediate, or frequent interventions and short, moderate, or longer duration.
- Pre-plan stoma site in order to promote adequate reach and self-care according to lying, sitting, standing, and belt line and to avoid bony prominences, scars, skin folds, and umbilicus.
- Evaluate for need for corrective surgery if stoma is fully retracted into peritoneum.
- Assess for leakage from appliance, infection, or hygiene mismanagement if patient reports odor and wet linens.
- If ureterosigmoidostomy conduit emits diarrhea, obtain clean urine sample for potassium or magnesium and determine need for anal sphincter retraining.
- Instruct patients how to control odor.
- Determine need for enterostomal therapist (ET) in clinic or home setting.
- Document severity of skin integrity disruption.

Terminal Care

Document optimal comfort measures and palliative care initiatives.

Discharge

Discharge from Case Management (CM)

 Document return to independence or stabilized functional status and closing conversations with patient, caregiver, physician, pharmacist, and care providers.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Overall Potential Benefits

Appropriate diagnosis, treatment, and management of benign and malignant kidney neoplasms that assist medical management leaders in making appropriate benefit coverage determinations

Specific Potential Benefits

- Computed tomography (CT) scan: Areas of fat identified in the tumor during abdominal CT are strongly predictive of angiomyolipoma diagnosis; abdominal CT provides staging information including extent of disease, information regarding liver metastasis, and inferior vena cava disease.
- Abdominal ultrasound (US): Abdominal US is useful in differentiating between cysts and masses.

POTENTIAL HARMS

Refer to the Case Management Focus section of the "Major Recommendations" field for information on potential complications and strategies to address them, or refer to the original guideline document.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

End of Life Care Getting Better Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Kidney neoplasms - benign and malignant. Philadelphia (PA): Intracorp; 2005. Various p. [18 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1997 (revised 2005)

GUIDELINE DEVELOPER(S)

Intracorp - Public For Profit Organization

SOURCE(S) OF FUNDING

Intracorp

GUIDELINE COMMITTEE

CIGNA Clinical Resources Unit (CRU)
Intracorp Disability Clinical Advisory Team (DCAT)
Medical Technology Assessment Committee (MTAC)
Intracorp Guideline Quality Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

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GUIDELINE AVAILABILITY

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Reprints of complete guideline content may be purchased for \$35.00 per title (plus tax in TX at 8.25% and CT at 1.0%). Please send e-mail request to lbowman@mail.intracorp.com.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

 Policies and procedures. Medical Technology Assessment Committee Review Process. Philadelphia (PA): Intracorp; 2004. 4 p. • Online guideline user trial. Register for Claims Toolbox access at www.intracorp.com.

Licensing information and pricing: Available from Intracorp, 1601 Chestnut Street, TL-09C, Philadelphia, PA 19192; e-mail: lbowman@mail.intracorp.com.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on May 25, 2005. The information was verified by the guideline developer on June 7, 2005.

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